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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FOLEY & LARDNER LLP 777 EAST WISCONSIN AVENUE MILWAUKEE, WI 53202-5306			EXAMINER STEWART, ALVIN J	
			ART UNIT 3774	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/730,606	Applicant(s) SWEENEY, PATRICK J.	
	Examiner Alvin J. Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-23 and 42-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 42-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites the limitation "the shaft" in line 2. There is insufficient antecedent basis for this limitation in the claim. The Examiner is not clear of which shaft the Applicant's representative is referring to. Is the first or second shaft?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Levisman US Patent 6,350,126 B1.

Levisman discloses a method of replacing a shaft (24) of a joint prosthesis (the Examiner interpreted a joint prosthesis as a prosthesis (1) joining the bone with an artificial tooth) having a

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body (2), a head (25) and a shaft (24) after the joint prosthesis has been implanted in a patient comprising: creating an access aperture (the access aperture is when the artificial tooth is broken (see col. 6, lines 5-9), removing the shaft from the patient without removing the body (see col. 6, lines 10-16 and inserting a new shaft into the patient (see col. 6, lines 16-20) and closing the access aperture by inserting the artificial tooth.

Claims 42-48, 50-69, 71, 73, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Ganjianpour 6,716,250.

Ganjianpour discloses the invention as currently claimed comprising: a body (40) having a central canal (see Fig. 8) and coupled to an articular surface (22, 44 & 46); extending there through; *a head coupled to the body (22)* ; a shaft (42) coupled to the body and extending through the central canal *and a replacement shaft (Ganjianpour discloses an implant having a plurality of shafts that have a plurality of different lengths and offsets that are provided to accommodate the needs of individual patients, see col. 1, lines 23-27; col. 6, lines 16-24 and lines 42-48; and cos. 7 & 8 lines 66-67 and 1 and 2) wherein the shaft is capable of being interchanged after implantation of the prosthesis by removing the shaft and replacing the shaft (42) with a replacement shaft without dislodging the body from the patient (all functional and capable of being performed by Ganjianpour; the Examiner wants to point out that the system is capable of replacing different shafts because the prior art clearly disclose a modular prosthesis having a plurality of shafts); wherein the shaft is coupled to the body via insertion of the shaft through an end of the central canal nearest an articular surface of the prosthesis; wherein the device is configured for a hip joint or shoulder joint (the device can be put into an animal of varying sizes to replace there shoulder joint); wherein the shaft is a nail.*

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Regarding claims 50, 51, 56, 57, element 48 is the insert.

Regarding claims 71, the Examiner interpreted the shaft removal device as element 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dwyer et al US Patent 7,122,056.

Dwyer et al discloses a method of replacing a shaft (12, see shaft in figure 6) of a joint prosthesis (10, 100 or 200) having a body (14), a head (26) and a shaft (12) after the joint prosthesis has been implanted in a patient comprising: creating an access aperture, removing the shaft from the patient without removing the body (see col. 6, lines 10-16 and inserting a new shaft into the patient (see col. 13, lines 32-41) and closing the access aperture.

The Dwyer et al is silent regarding the opening and closing of the access aperture, however, it is an inherent characteristic to open the patient's body in order to replace a damage joint and close the patient's body after the surgeon finished fixing the damaged joint.

Additionally, Dwyer et al is silent regarding the replacement of only the shaft (12) and not of the body (14) and the distal stem element 18.

Col. 13, lines 32-41, clearly discloses all the elements, for example, shaft (12), body (14), element 16 can be replaced. The shaft can be longer than the original shaft. The design of the Dwyer et al reference clearly discloses one and only one step of connecting all the parts

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(elements 12, 14 and 18) together. For example, the connecting step is installing element 12 over and inside element 14 and connecting element 32 and 34 inside element 18, see Figure 2 (see col. 6, lines 31-53). If this is correct, then the device is capable of replacing element 12 without removing element 14 from an implanted site.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to only replace the prosthetic component that need to be changed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shaft (12) of the implant and maintain the bore (14) and the distal stem element 18 within the bone in order to replace a damage implant.

Regarding claim 23, it would be obvious to one having ordinary skill in the art to modify the replacement shaft by a second shaft longer than the first shaft in order to meet the considerations of each individual patient and different implantation applications.

Claims 49, 70 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganjianpour US Patent 6,716,250 B2.

Ganjianpour discloses the invention substantially as claimed. However, Ganjianpour does not clearly disclose a second shaft longer than the first shaft. Regarding claim 75, the Examiner interpreted the claim as follow: body (40), head (22), shafts (42), locking element (48), shaft removal device (inherent to have a screw driver to lock element 48 to screw bore (36) in element 40.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the second shaft by having a second longer shaft for the purpose of meeting different considerations of each individual patient and

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different implantation applications(see col. 6, lines 42-48) because Applicant has not disclosed that by having a second longer shaft provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with same shaft length because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Ganjianpour reference to obtain the invention as specified in claims 49, 70 and 75.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ganjianpour US Patent 6,716,250 B2 in view of Levisman US Patent 6,350,126.

Ganjianpour disclose the invention substantially as claimed. However, Ganjianpour does not disclose a shaft having a threaded recess configured to be screwed to the shaft removal device (48).

Levisman teaches an implant having a body (2), a head (25), and a shaft (24) capable of being replaced by a second shaft (as disclosed above) and a shaft screw to a threaded recess for the purpose of preventing the rotation of the two above elements (see col. 5, lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Ganjianpour reference with the Levisman reference in order to prevent the movement and rotation of the shaft with respect to the shaft removal device (48).

Response to Arguments

Applicant's arguments filed 9/04/2007 have been fully considered but they are not persuasive.

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The Applicant's representative discloses that the Levisman reference does not identically disclose a method including removing a shaft without removing the body or the head. Additionally, the Applicant's representative discloses a prosthesis wherein it is possible to remove a "stud" (identified as "head" by the Examiner) without removing a body but the removal of "stud 24" necessitates the removal of the abutment 25. Therefore, the Levisman reference does not anticipate the previous rejected claims.

Regarding the above matter, the Examiner completely disagrees with the Applicant's representative arguments. For example, claim 19 clearly disclose that the shaft can be removed from the patient without removing one and only one of the body or the head. Nowhere in the claim disclosed that the shaft has to be removed with the head. Therefore, the Examiner interpreted the claim as the shaft (24) can be replaced without removing the body (2).

Regarding the Dwyer et al reference, the Examiner believes that the 103(a) rejection is still proper. As mentioned above, the Dwyer et al reference, clearly discloses all the elements, for example, shaft (12), body (14), element 16 can be replaced. The design of the Dwyer et al reference clearly discloses one and only one step of connecting all the parts (elements 12, 14 and 18) together. For example, the connecting step is installing element 12 over and inside element 14 and connecting element 32 and 34 inside element 18, see Figure 2 (see col. 6, lines 31-53). If this is correct, then the device is capable of replacing element 12 without removing element 14 from an implanted site (see col. 13, lines 31-42).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A. Stewart

**ALVIN J. STEWART
PRIMARY EXAMINER**

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November 23, 2007.